UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON,
Plaintiff,

v.

CIVIL ACTION NO. 3:17-01362

AMERISOURCEBERGEN DRUG CORPORATION, et al.,
Defendants.

CABELL COUNTY COMMISSION,
Plaintiff,

v.

CIVIL ACTION NO. 3:17-01665

AMERISOURCEBERGEN DRUG CORPORATION, et al.,
Defendants.

PLAINTIFFS' REPLY IN SUPPORT OF MOTION *IN LIMINE* TO PRECLUDE ANY REFERENCE TO THE DEA APPROVING OR ENDORSING A PARTICULAR DEFENDANT'S SOM PROGRAM

Plaintiffs moved to preclude testimony or evidence that the U.S. Drug Enforcement Agency ("DEA") granted "approval" of any particular Defendant's Suspicious Order Monitoring ("SOM") program because the scope of Defendants' duties under the Controlled Substances Act ("CSA") and DEA regulations is a pure question of law, and any testimony purporting to state a legal conclusion about a Defendant's SOM program is not admissible.

Defendants do not dispute either of these propositions. Nor do they contend that DEA even has authority to grant "approval" of their SOM programs, an authority that DEA itself disavows having. *See* Pltfs' Ex's A-B (DEA December 27, 2007 and June 12, 2012 letters) (ECF No. 1353-

1, 1353-2).[1] They nevertheless argue that evidence of an ostensible DEA approval is admissible for three reasons. They contend that this is relevant to whether their distribution conduct at issue was reasonable, that Plaintiffs opened the door to this evidence based on their questioning of one of Defendants' witnesses, and that Plaintiffs waived any objection to this type of evidence by failing to object to one of Defendants' questioning of the same witness. Each of these arguments is incorrect and should be rejected for the reasons set forth below.

First, evidence of an ostensible DEA approval of a Defendant's SOM program is not relevant or generally admissible. The scope of Defendants' duties under the CSA and DEA regulations is a pure question of law,[2] and "testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."[3]

Defendants nonetheless argue that this evidence is admissible as relevant to the reasonableness of their conduct or to questions of their knowledge and intent. *See* Defendants' Opposition ("Opp.") (ECF No. 1361) at 4-5. As to reasonableness, Defendants focus more broadly on "DEA's awareness of Defendants' SOM programs and its communications with Defendants about those programs . . . ." *Id.* at 4. Plaintiffs do not, however, seek to exclude all

[1] *Cf.* 21 U.S.C. § 355(a) (requirement for Food and Drug Administration ("FDA") approval for new drug to be introduced into interstate commerce); 21 U.S.C. § 360c(a)(1)(C) (requirement for FDA premarket approval for Class III medical device). Even these FDA approval regimes raise critical questions about what the meaning of an authorized approval is on a forward-going basis as more information becomes available about the approved matter. *See* Kessler and Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L.J. 461, 471 (Jan. 2008) ("The FDA's approval of a drug does not spell the end of the agency's oversight of the drug or its labeling. Prior to FDA approval, drugs are tested on relatively small populations of patients, for durations rarely exceeding a year or two. Thus, pre-approval testing generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies . . . . For these reasons, the FDA's approval of a drug is not a warrant that the drug will not cause serious adverse effects even if properly used for its approved purposes."). Here, Defendants' evidence of purported DEA approval should be of no relevance because it is their implementation and operation of their SOM programs that determine their effectiveness and reasonableness. *See* Plaintiffs' Ex. A (ECF No. 1353-1) at 1 ("The regulation clearly indicates that it is the solely responsibility of the registrant to design and operate such a system.").

[2] *See*, *e.g.*, *United States v. Moriello*, 980 F.2d. 924, 934 (4th Cir. 2020) ("Regulatory interpretation is a question of law.").

[3] *United States v. McIver*, 470 F.3d 550, 561-62 (4th Cir. 2006); *see also* Memo. Op. and Order excluding expert opinions of James Geldhof (ECF No. 1269) at 4-5 (testimony on "the content of the law" and "how the law applies to defendants" is "not helpful because the court is capable of understanding the law at issue here.").

communications between Defendants and DEA about Defendants' SOM programs. They seek to preclude evidence that DEA actually "approved" any program when it has no authority to do so. This is precisely where Judge Polster drew the line in the MDL, recognizing the lack of evidentiary value of such incorrect statements of law. *See* MDL *Nunc Pro Tunc* Evid. Order (MDL ECF No. 3058) at 23 n.46 ("Further, any statements by DEA agents that contradict the requirements of the [CSA] or otherwise misstate the law will be subject to exclusion.").

Defendants thus fall back to arguing that "[s]tatements by DEA approving or endorsing a SOM program may be relevant to show Defendants' ***state of mind*** regarding their regulatory compliance." *Id.* at 5 (emphasis in original). This, however, runs afoul of this Court's prior ruling and consistent West Virginia and Fourth Circuit authority holding that knowledge and intent are determined by knowledge of the *facts* of one's conduct, not of its unlawfulness or resulting harms. *See* Memo. Op. and Order re Fault (ECF No. 1294) at 5-6 (rejecting Defendants' argument that "intent, in this context, means intent to create the alleged harms resulting from the alleged oversupply of prescription opioids") (citing *Hendricks v. Stalnaker*, 380 S.E.2d 198, 202 (W. Va. 1989)); *see also U.S. v. Fuller*, 162 F.3d 256, 260 (4th Cir. 1998) ("To act 'knowingly' is to act with 'knowledge *of the facts* that constitute the offense' but not necessarily with knowledge that the facts amount to *illegal* conduct, unless the statute indicates otherwise.") (quoting *Bryan v. U.S.*, 524 U.S. 184, 192-93) (emphasis in original). Thus, testimony about a DEA "approval" that the agency had no authority to grant is not relevant to any issue in the case and should be excluded.[4]

Second, Plaintiffs did not open the door to allowing testimony that DEA granted an approval is has no authority to grant. Defendants contend that Plaintiffs opened the door by introducing a DEA letter that specifically *disavowed* this authority. *See* Opp. at 3 (quoting DEA's

[4] To the extent the Court rules otherwise that such evidence may be relevant to show Defendants' intent, Plaintiffs request that the evidence only be admitted where this is shown.

December 27, 2007 Dear Registrant Letter (ECF No. 1353-1) ("Past communications with DEA . . . should no longer be taken to mean that DEA approves a specific system.")); *see also* Trial Tr. (May 13, 2021) at 217:19-218:11 (admitting P-521, DEA August 4, 2007 letter stating that: "The [settlement] agreement does not approve or endorse [a] particular system to identify and disclose suspicious orders. The design and operation of a particular system remains the sole responsibility of ABDC."). These letters thus should close and lock rather than open any door to testimony that the DEA did or could grant an approval of any Defendant's SOM program.

Seeming to recognize this, Defendants turn to Plaintiffs' questioning of ABDC witness Chris Zimmerman about DEA communications. *See* Opp. at 3-4. Plaintiffs' questioning, however, addressed the existence of written communications on one monitoring factor, and not whether DEA did or could grant approval of a SOM program. *See* Trial Tr. (May 13, 2021) at 55:24-56:2 ("Do you have anything in writing where the DEA has ever said to AmerisourceBergen that it approves using a multiplier for purposes of monitoring suspicious orders of controlled substances?"). This did not open the door to allowing testimony on an incorrect legal conclusion that DEA did or could approve any Defendant's SOM program. *See generally U.S. v. Chance*, 306 F.3d 356, 385 (6th Cir. 2002) ("[W]here one party has 'opened the door' on an issue, the opponent, in the trial court's discretion, may introduce evidence *on the same issue* to rebut any false impression that may have been created by the earlier admission of evidence.") (emphasis added); *Doolittle v. Director, DCJ-CID*, No. 5:10-cv-228, 2013 WL 3992406, at *3 (E.D. Tex. Aug. 2, 2013) ("[I]nadmissible evidence may be admitted if the defendant opened the door, as long as the evidence does not go beyond the scope of the invitation.").

Third, Plaintiffs did not waive their objection to testimony that DEA did or could grant approval of a Defendant's SOM program. Mr. Zimmerman's reading from a DEA letter purporting

to state such an approval, *see* Trial Tr. (May 13, 2021) at 182: 12-20, that DEA itself disavows the authority to grant does not mean that Plaintiffs waived their objection to testimony that a Defendant's SOM program actually is DEA-approved when it is not.

CONCLUSION

For all of the reasons set forth, the Court should exclude any further reference to the DEA approving or endorsing a particular Defendant's SOM program.

Dated: May 21, 2021

Respectfully submitted,

THE CITY OF HUNTINGTON

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CERTIFICATE OF SERVICE

I certify that on May 21, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ *Anthony J. Majestro*